Remarks

Claims 1, 2, 4-18, 21-26, 29-60, 62, 67-78, and 80-91 remain in the present application. A Petition for Extension of Time is Enclosed with this Response and the Assistant Commissioner for Patents is authorized to charge payment to Frost Brown Todd LLC Deposit Account No. 06-2226.

In response to the Office Action dated September 9, 2002, setting forth a restriction requirement under 35 U.S.C. § 121, please consider the following remarks:

The Examiner has pointed out an error in the claim number of the previous amendment and response and renumber the new claims accordingly. Applicants appreciate Examiner's assistance in this matter.

In addition, the Examiner notes that "claim 33 is dependent on the cancelled claim 28; therefore the nature of this claim is not clearly determined to be restricted" in the restriction detailed below. Applicants appreciate Examiner's assistance in pointing out that a previous amendment was not entered for this claim. Claim 33 has now been amended to depend upon the pending claim 26. The basis for the amendment to this claim can be found on pages 21-23 and further on pages 47-62 of the specification.

Restriction/Elections

The Examiner now contends that the application contains the following eight independent inventions:

Group I, claims 1-2, 4-18, 21-26, 29-32, 34-35, 42-46, 60, 62, 74-76 and 81-91, drawn to methods of increasing immune recognition of a mammalian cell in the subject; methods for presenting antigen to the immune system of a mammal; utilizing cells obtained from the subject to the mammal that have been transfected with a sequence nonspecific double-stranded polynucleotides > 25 nucleotides.

Group II, claims 77-78, 80, and 89-91, drawn to a vaccine for treating cancer comprising an adjuvant comprising a sequence nonspecific double-stranded polynucleotides > 25 nucleotides in length, an antigen of interest, a pharmaceutically acceptable carrier, and a method for augmenting a vaccine response using the same.

Group III, claims 36-39 and 55-56, drawn to a screening method for a drug to

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regulate antigen presentation or a method of screening a compound that regulates the effect of double-stranded polynucleotides.

Group IV, claims 40, drawn to a pharmaceutical composition.

Group V, claims 41, drawn to a DNA molecule comprising at least one of Seq. ID Nos. 1-16.

Group VI, claims 47-54, drawn to a method of identifying differential expression of a sequence expressed in response to a double-stranded polynucleotide.

Group VII, claims 57-59, drawn to methods of screening for a compound that regulates the effect of double-stranded polynucleotides utilizing an animal immunized with an immune cell transfected with an antigen and a double-stranded polynucleotide.

Group VIII, claims 67-73, drawn to a method to assess viral replication comprising measuring and comparing the level of expression of the gene which is affected by transfection with double-stranded polynucleotides in a cell.

This restriction requirement is hereby respectfully traversed. This restriction requirement is improper for numerous reasons, as follows:

All of the claims in the present application involve the same basic ingredients: (a) obtaining a cell and (b) introducing a sequence nonspecific double-stranded polynucleotide greater than 25 nucleotides in length into the cell and thereby activating expression of a gene or gene product, wherein such activation is involved in antigen presentation, growth, and function of the cell, and which increases the ability of a cell to present antigen.

The Examiner has provided no basis supporting the restriction/election requirement given that each and every claim of the present invention requires this common inventive element.

In order to search any of the present claims, the Examiner will have to search the immune activation art. The art is a very well defined, relatively small field. MPEP §803 states that even if an application includes several independent or distinct

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inventions, they should all be considered together in a single prosecution if that can be done without placing a serious burden on the Examiner. Even if it is assumed that the claims of the present invention cover more than one distinct invention, they should all be considered together since largely the same art would have to be searched for each claim. Therefore, considering all claims together would not place a serious burden on the Examiner.

For these reasons, the restriction requirement defined by the Examiner is improper. Accordingly, it is respectfully requested that the restriction requirement be withdrawn. The Examiner is urged to reconsider the restriction/election requirement.

If the event the Examiner maintains the restriction/election requirement, the Applicants elect the following:

Applicants hereby elect **Group I** with traverse and select the proper species as required by the Examiner as described below.

In electing Group I, applicants select among the following subgroups:

A.) Applicants elect a somatic cell as the species of a mammalian cell in selecting between (a) a somatic cell; (b) an antigen presenting cell; and (c) a thyroid cell. In order to select species (a), Applicants elect a fibroblast as a distinct species between (i) a tumor cell; and (ii) a fibroblast.

B.) Applicants elect transfection as the species of methods for introducing the sequence into a cell selecting between transfection, microinjection, viral infection of the cell, phagocytosis of a bacterium, phagocytosis of a virus, phagocytosis of a cell, and oncogene transformation.

C.) Applicants elect the polynucleotide does not contain a stimulatory CpG motif as a species of nonspecific double-stranded polynucleotides selecting between (a) where the polynucleotides do not contain a stimulatory CpG motif; and (b) the polynucleotide contains one or more CpG motifs.

D.) Furthermore, applicants elect MHC class I as the species of gene or gene product associated with increased immune activation selecting between MHC class I, MHC class II, TAP-1, TAP-2, a proteosome subunit, HLA-DM, invariant chain, RFXA, B7 co-stimulatory molecule, PKR, MAP kinase, NF-kB, JAK, and

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STAT genes and gene products.

It is Applicants' understanding that if the above-elected species are found patentable, the Examiner will search the entire breadth of the present invention as defined in the application.

Applicants' undersigned attorney has made a good faith effort to be responsive to the restriction requirement made in the Office Action dated September 9, 2002. If the Examiner would like to discuss the restriction requirement or to have applicants provide any clarification of its terms, he is invited to contact Applicant's undersigned attorney at the phone number given below.

The Assistant Commissioner for Patents is authorized to charge any deficiency or credit any overpayment to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

Kohn, *et al.*

By _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE SPECIFICATION:

IN THE CLAIMS:

Please amend the following claims as indicated:

33. (once amended) The method of claim 26 [28] wherein the double-stranded polynucleotide comes from the mammalian cell's nucleus or mitochondria.

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CERTIFCATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below:

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Attn: Quang Nguyen

Art Unit No.: 1636

Serial No. 09/151,612

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